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Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett
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1300 I Street, N.W.
Washington, D.C. 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,015,247

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,015,247, which claims the medical device BAK Interbody Fusion System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 829 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 829 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 30, 1997 (62 Fed. Reg. 40829). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (1,341) + 390 \\ &= 1,061 \text{ days}\end{aligned}$$

Since the regulatory review period began December 27, 1991, after the patent issued (May 14, 1991), the entire period has been used in the above-determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,061 days, would extend the patent from June 13, 2008 (35 U.S.C. § 154) to May 10, 2011, which is beyond the 14-year limit (the approval date is September 20, 1996, thus the 14 year limit is September 20, 2010). The period of extension is thus limited to September 20, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 13, 2008, to and including September 20, 2010, or 829 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

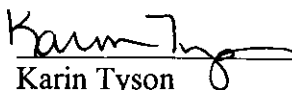
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,015,247
Granted:	May 14, 1991
Original Expiration Date ¹ :	June 13, 2008
Applicant:	Gary K. Michelson
Owner of Record:	Karlin Technology, Inc.
Title:	Threaded Spinal Implant
Classification:	606/61
Product Trade Name:	BAK Interbody Fusion System
Term Extended:	829 days
Expiration Date of Extension:	September 20, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents	By FAX:	(703) 308-6916
	Box Patent Ext.		Attn: Special Program Law Office
	Washington, D.C. 20231		

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: BAK Interbody Fusion System
FDA Docket No.: 96E-0502

¹Subject to the provisions of 35 U.S.C. § 41(b)